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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,908	12/04/2001	Nissim Darvish	015/02481	3374

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EXAMINER
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MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 09/980,908	Applicant(s) DARVISH ET AL.	
	Examiner George Manuel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-18, 20-58, 60-63, 65, 66 and 68-70 is/are rejected.
- 7) ☒ Claim(s) 10, 19, 59, 64, 67 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-18, 20-58, 60-63, 65, 66, 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/15317.

WO 98/15317 discloses an electrode 10 and a power source 30. One of ordinary skill in the art would have found it obvious to program the switches S1-S4 to effect transporting a molecule from electrode tip 14 to the heart because page 13 teaches the magnitude of a dose is proportional a charge imbalance. Further, page 11 teaches precise control can be maintained over the dosage of the delivered drug based on Faraday's Law of Electrolysis.

Regarding claims 8, 30, 31 and 43-46, one of ordinary skill in the art would have found it obvious to monitor the effects the applied fields and patient drug interaction because it is well known to monitor patient drug therapies for adverse reactions.

Regarding claim 63, the examiner is interpreting the lead system to comprise a catheter.

Regarding Applicant's remarks, filed 9/22/04, WO 98/15317 is capable of both discharging a pacing pulse when drug 18 should not be released from matrix 22 (page 13, lines 5-14) and when iontophoretic drug deliver is desired (page 13, lines 15-31). The teaching for drug delivery clearly shows a non-excitatory control effect when DC-blocking capacitor 34 is short circuited and switch S3 and switch S2 are opened. Further, page 10, lines 19-20 teach the implanted device may be programmed for a variety of drug-deliver protocols. A non-excitatory drug-delivery protocol would be obvious to one of ordinary skill in the art because WO 98/15317 teach it is possible to utilize a neutrally charged reservoir/matrix (see page 5, line 1).

Additionally, a heart does not respond to pacing during a refractory period, and therefore, the cardiac stimulation provided by WO 98/15317 would be non-excitatory.

***Allowable Subject Matter***

Claims 10, 19, 59, 64 and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (703) 308-2118.

  
George Manuel  
Primary Examiner  
Art Unit: 3762